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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,977	08/22/2003	Jeffrey S. Kiel	PEDI-16	8380

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,977	KIEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *22-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 53* is/are rejected.

7)☒ Claim(s) *1, 18, 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *See Attached Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Information Disclosure Statement(s): January 6, 2004 (one page total); January 8, 2004 (one page total); and November 15, 2004 (one page total).

DETAILED ACTION

Claims 1-53 are presented for examination.

Acknowledgement is made of the present application as a continuation-in-part (CIP) of U.S. Patent Application No. 10/047,578, filed October 26, 2001, which is pending before the Office. Applicant's Information Disclosure Statements (IDS) filed January 6, 2004 (one page), January 8, 2004 (one page), and November 15, 2004 (one page) have each been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (three pages total), the Examiner has considered the cited references. Applicant's response filed January 4, 2006 to the restriction requirement dated December 5, 2005 has also been received and entered into the application.

Requirement for Restriction/Election

Applicant's election **with traverse** of Group I (claims 1-21 and 53), drawn to a composition comprising phenylephrine, pyrilamine and dextromethorphan, in the reply filed on January 4, 2006 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, **the election has been treated as an election without traverse** (MPEP § 818.03(a)). Thus, for the reasons of record set forth in the previous Office Action dated December 5, 2005 at pages 2-7, the requirement for restriction/election is hereby made **FINAL**.

Claims 22-52 are **withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

The claims corresponding to the elected subject matter are 1-21 and 53 and such claims

are herein acted on the merits.

Applicant's Claim for Priority Under 35 U.S.C. §120

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. §120 is acknowledged. Applicant is reminded that the later-filed application must be an application for patent for an invention that has been disclosed in the parent application. The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant has failed to comply with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 because the subject matter disclosed in U.S. Patent Application No. 10/047,578, filed October 26, 2001 does not contain sufficient support and enablement as required under 35 U.S.C. 112, first paragraph, for the presently claimed subject matter. Specifically, the disclosure of the application to which the present application claims priority does not reasonably disclose or suggest a composition comprising phenylephrine, pyrilamine and dextromethorphan. Accordingly, Applicant's claim for priority to U.S. Patent Application No. 10/047,578 is, respectfully, denied. Claims 1-21 and 53 are properly granted the effective filing date of the filing date of the present application (August 22, 2003).

Objections to the Claims

Claims 1 and 53 are objected to for reciting, for example, "a." to delineate a step of the process of forming the claimed product. Proper claim construction dictates that only one period

should appear at the conclusion of a claim, unless it is used to denote a decimal point in a number within the claim. Applicant may wish to consider changing the letters "a.", "b.", "c.", "d.", and "e." to "a)", "b)", "c)", "d)", and "e)" in order to obviate this objection.

Claim 18 is objected to for failing to define the acronym "MAS" at its first occurrence in the claims, which is defined at page 8 of the specification as "magnesium aluminum silicate".

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 1-13, 16-21 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the use of the terms "first solvent", "first solution", "second solvent", "second solution" or "first dispersion", as recited in claim 1, are terms that render the claims indefinite. The identity of such "first" or "second" solvents, "first" or "second" solutions or "first" dispersion that result from executing the claimed process steps are not defined by the claims, nor does the specification provide any direction as to what "first" or "second" solvents, "first" or "second" solutions or "first" dispersion may be used in order to ultimately produce a liquid dosage form of pharmaceutically active tannate salts of the active agent phenylephrine, pyrilamine and dextromethorphan.

For example, there are a large and varied number of "solvents" that are known in the art and could very well fall into the scope of Applicant's claims, but would not necessarily be those

that would be amenable for use as the "first solvent", for example, in the claimed process of forming a tannate salt-containing liquid dosage form. The general use of the word "solvent" indicates that any known solvent may be used, organic or inorganic, in this claimed process. However, it is reasonably concluded that not all solvents known in the art would be appropriate for use in this claimed process. In the absence of any direction or definition as to the identity of the "first" or "second" solvents, "first" or "second" solutions or "first" dispersion may be used in the claimed process, the metes and bounds of the claims cannot be identified and, thus, such a deficiency renders the scope of the claims indefinite under 35 U.S.C. 112, second paragraph.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, thus, properly rejected.

II Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that the subject matter of claim 3 is drawn to wherein "the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, hydrochloride, hydrobromide, acetate and sulfate" as recited in lines 1-3 of the claim. However, it is not clear whether the limitations set forth in present claim 3 is intended to limit the process as set forth in claim 1 or the composition as set forth in claim 1.

Applicant is presently claiming a composition, wherein the composition is a liquid dosage form, such as a suspension, and comprises tannate salts of the pharmaceutical active ingredients phenylephrine, pyrilamine and dextromethorphan. However, if such a claim were

intended to limit the composition, it is not clear how Applicant could now claim a composition wherein the active pharmaceutical ingredients are any one of maleate, citrate, hydrochloride, hydrobromide, acetate or sulfate salts, if the claimed end product is a composition wherein the active pharmaceutical ingredients are tannate salts.

However, if such a claim were intended to limit the process, it is not clear to what step the claim refers back. For example, it is unclear as to whether the active pharmaceutical ingredients used in the very first step of the process are any one of maleate, citrate, hydrochloride, hydrobromide, acetate or sulfate salts, or if the salts formed from the mixture of the solvents, solutions and dispersion are to form any one of maleate, citrate, hydrochloride, hydrobromide, acetate or sulfate salts, such that the end product of the process is not a tannate salt, but rather any one of the above-listed salts. Absent any clear delineation of the subject matter this claim intends to limit, the metes and bounds of the claimed subject matter cannot be determined.

It is suggested that Applicant may wish to amend the claims to make clear what Applicant actually intends to claim, i.e., whether such a limitation is intended to limit the composition or the process by which the composition is formed, and what step of the process it is intended to limit, if appropriate.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination and the application of prior art, the subject matter of claim 3 will be interpreted to limit the process by which the composition is formed.

III Claims 2, 6-8 and 10-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expression "of about 0.05% to about 25.0% by weight" as recited in present claim 2, for example, is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular percentage, pH value, or dosage amount of the active ingredients is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims.

Furthermore, the Examiner also has noted the word "of" in present claim 2, for example. In such a case, the word "of" in the phrase "of about 0.05% to about 25.0% by weight" indicates that the weight percent is between 0.05% and 25.0%. However, the use of the word "about" denotes that the weight percent may be slightly greater or slightly less than 0.05%, for example, or 25.0%, for example. Thus, it is not clear which is meant to be the limiting term. It is the Examiner's position that the public would not be informed of the boundaries of what constitutes

infringement of the present claims.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, thus, properly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-8, 10-18, 21 and 53 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Venkataraman (U.S. Patent No. 6,509,492; Issued January 2003, Filed September 2001).

Venkataraman teaches compositions comprising combinations of two or more therapeutic agents (col.10, lines 4-5), preferably compositions comprising tannate salts of a combination of an antihistamine, a decongestant and an antitussive (col.10, lines 4-13, particularly lines 7-8), preferably wherein the composition is in the form of a suspension (col.2, lines 3-10 and col.19, lines 35-41; see present claims 1 and 21), and wherein the antihistamine may be pyrilamine

tannate (see Table 1 at col.6; see present claims 1, 3-8, 10-18, 21 and 53), the decongestant may be phenylephrine tannate (see Table 1 at col.7; see present claims 1, 3-8, 10-18, 21 and 53) and the cough suppressant/antitussive may be dextromethorphan tannate (see Table 1 at col.7; see present claims 1, 3-8, 10-18, 21 and 53).

While all of the limitations of the instant claims have been considered, it is noted that the present claims are "product-by-process" type claims. The limitations of claim 1, denoted as parts (a) through (e), and the limitations of each of claims 3-8 and 10-18 are each considered to be limitations that define the process by which the product is made and, thus, do not impart any physical or material property to the composition that is not already present. Regarding this type of claim, Applicant's attention is drawn to the MPEP at §2113, which states:

"[E]ven though product-by-process claims are limited by and defined by the process, ***determination of patentability is based on the product itself***. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)." (emphasis added)

The structure implied by the process steps of the present claims has been considered by the Examiner, but fails to impart distinctive structural characteristics to the final product (see MPEP §2113). The present claims require, in their simplest form, dissolution and mixing of the physical components recited in the claims to form a liquid dosage formulation, in particular, a suspension (see present claim 21), of the tannate salts of phenylephrine, pyrilamine and dextromethorphan. Applicant's attention is drawn to Venkataraman at column 2, lines 3-10, which particularly describes that the disclosed composition may be in the form of a sterile solution or suspension. Thus, because the structure of the final product of the present claims is not considered to differ from that of the prior art, the process by which the present claimed product is made does not impart any physical or structural property to the composition that is not already found in the composition disclosed by Venkataraman, and, thus, the presently claimed process is not a patentable distinction between the products.

In the absence of any factual evidence or direction to the contrary, the presently claimed composition is considered substantially identical to that of the prior art of Venkataraman, since the reference discloses each of the required physical components of the presently claimed product. In this regard, the MPEP directs at §§2112.01(I) and 2113:

"Where the claimed and prior art products are identical or substantially identical in structure or composition...a *prima facie* case of either anticipation or obviousness has been established...When the PTO shows a sound basis for believing that the products of the Applicant and the prior art are the same, the Applicant has the burden of showing that they are not." (see MPEP §2112.01(I))... "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different

process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.*" (see MPEP §2113; emphasis added)

Lastly, it is again noted, for clarification, that the limitations of present claims 3-8 and 10-18 limit the process, not the composition, and, therefore, fail to impart any physical or structural property to the claimed composition of phenylephrine, pyrilamine and dextromethorphan. For this reason, such claims are properly rejected under 35 U.S.C. 102(a) or 102(e), since the process by which the claimed composition (i.e., product) is made fails to convey any patentable moment to the product that distinguishes the composition from the prior art product of Venkataraman.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (U.S. Patent No. 6,509,492; Issued January 2003, Filed September 2001).

The differences between the Venkataraman reference and the presently claimed subject matter lies in that the reference fails to teach the presently claimed wt% or mg dosage amounts of the active pharmaceutical ingredients of the composition or the pH of the composition between 3.5 and 6.5.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. In particular, the determination of the optimum wt% and dosage amounts of the presently claimed active pharmaceutical ingredients that comprise the composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the wt% or dosage amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific wt% or dosage amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

Furthermore, the determination of the optimum pH of the claimed liquid dosage form would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional Rejection

Claims 1-21 and 53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21, 31-48 and 53 of U.S. Patent Application No. 10/047,578. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending patent application are not considered patentably distinct from each other because the present claims render the copending claims obvious.

The present claims clearly provide for a composition consisting essentially of phenylephrine and pyrilamine (see present claim). While it is noted that the copending claims recite "consisting essentially of", regarding the use of the transitional phrase "consisting essentially of", the MPEP states at §2111.03, "The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially

affect the basic and novel characteristic(s)" of the claimed invention...For the purposes of searching for and applying prior art under 35 U.S.C. §102 and §103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." Absent factual evidence to the contrary, and in light of the fact that Applicant has failed to define the basic and novel characteristics of the invention, the copending claims have been interpreted to read upon the transitional phrase "comprising". Thus, the claims do not patentably exclude the use of additional components in the composition, as provided for in the present claims. As previously stated, regardless of the transitional language used, such does not change the fact that the present claims clearly provide for a composition of phenylephrine and pyrilamine.

The process recited in the present claims is substantially identical to the process recited in the copending claims, but for a few minor differences. However, it is again noted that, regarding product-by-process claims, the MPEP states at §2113, "[E]ven though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production." (emphasis added) Thus, regardless of the minor differences in the process of the present claims and that of the copending claims, such differences do not change the fact that the product of the present claims clearly renders the product of the copending claims obvious, regardless of the way it was produced. Since the process fails to convey any patentable moment to a product, the product of the copending claims is obvious from that of the present claims and the present rejection is, thus, proper.

Accordingly, rejection of claims 1-21 and 53 of the present application is deemed proper over claims 1-21, 31-48 and 53 of U.S. Patent Application No. 10/047,578 as claiming obvious and unpatentable variants thereof.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 3,282,789 to Marty et al. ("Stable Liquid Colloidal Tannate Compositions") and U.S. Patent No. 5,759,579 to Singh et al. ("Pharmaceutical Suspension Systems").

Rejection of claims 1-21 and 53 is deemed proper.

Claims 22-52 are **withdrawn** pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

February 6, 2006

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